DETAILED ACTION

Response to Amendment

1. Applicant's preliminary amendment filed December 2nd, 2008 is acknowledged. Currently, claims 1-3 and 5-21 are pending with claims 1, 5-7, 9, 11 and 20 amended, claim 21 newly added and claim 4 cancelled. The following is a complete response to the December 2nd, 2009 communication.

Information Disclosure Statement

2. The information disclosure statement filed June 4th, 2008 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the ***English language***. The lined through application fails to have any translated portion included with its submission. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3, 5, 7, 9-13, 16 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Cosmescu (US Pat. No. 6,149,648).

Regarding claim 1, Cosmescu discloses an apparatus for coagulating tissue (as best shown in figure 6-6C and 8A) comprising an electrode (electrode **112/436**) capable of producing

a high-frequency current, a gas-delivering device (tube **152**) having an outlet (near distal flared end at **154**) and being capable of delivering an inert gas (supplied from proximal connector **162**) from the outlet into a space defined between the electrode and the tissue such that a plasma is produced between the electrode and the tissue when the high frequency current is applied to the inert gas (argon beam, see col. 13; 43-52) wherein a distal end of the electrode projects out of the gas-delivering device (see arrangement in figures 5 and 8A) and a guiding device disposed at the distal end of the electrode (enlarged portion of electrode **112/436**, ball shape at end of electrode in figure 8D) at distal end of electrode wherein the guiding device functions to direct and guide at least one of the gas and the plasma such that at least a part of the gas and plasma is diverted in a predetermined direction (enlarged portion affecting outputted flow).

Regarding claim 3, Cosmescu discloses the electrode **112/436** and its enlarged distal portion functioning as the guiding device to be electrically conductive and to provide radiofrequency treatment and/or argon plasma treatment to a target site (see col. 13; 23- col. 15; 5). As such, it would be inherent that such an electrode assembly as that of Cosmescu would be comprised of a thermally stable material in order to provide the disclosed treatment.

Regarding claim 5, Cosmescu discloses that the guiding device is configured such that the gas flows into the space substantially radially with respect to the outlet of the gas- delivering device (gas exiting and flowing into radial space defined between target tissue and electrode **112/436**).

Regarding claim 7, Cosmescu discloses that the guiding device has a contour which prevents mechanical damage if the guiding device touches the tissue (rounder outer configuration of electrode **112/436** in figure 6A, ball shape of electrode in figure 8D).

Regarding claim 21, Cosmescu discloses that the guiding device has a rounded contour (rounded tube-shape of electrode **112/436** in figure 6A and ball-shape of electrode in figure 8D).

Regarding claim 9, Cosmescu discloses an apparatus for coagulating tissue (as best shown in figure 6-6C and 8A) comprising a gas-delivering device (tube **152**, see figure 5), an electrode disposed substantially coaxially with the gas-delivering device (electrode **112/436**, see figures 5 and 6A) and functioning to generate a high-frequency current wherein a distal end of the electrode projects outward through an outlet of the gas-delivering device (see arrangement of electrode in figures 5 and 8A) and a guiding device disposed at the distal end of the electrode (enlarged portion of electrode **112/436**, see figures 6A and 8C-D) wherein the guiding device is functions to guide an inert gas stream flowing through the gas-delivering device (enlarged portion affecting outputted flow).

Regarding claim 10, Cosmescu discloses that the guiding device is disposed in an axially symmetric manner around the distal end of the electrode (see arrangement of electrode/guiding device in figures 6A and 8C-D).

Regarding claim 11, Cosmescu discloses that the guiding device functions such that the inert gas stream is guided into a surrounding space substantially radially with respect to the outlet of the gas delivering device (gas exiting and flowing into radial space defined between target tissue and electrode **112/436**).

Regarding claim 12, Cosmescu discloses that the guiding device is shaped such that damage to the tissue is prevented if the guiding device touches the tissue (rounder tube-shape of electrode **112** in figure 6A/8C and ball-shape in figure 8D).

Regarding claim 13, Cosmescu discloses the guiding device to be spherical (see distal end shape of electrode **436** in figure 8D).

Regarding claim 16, Cosmescu discloses that the electrode is configured such that it may be retracted and pushed forward with respect to the gas-delivering device (see col. 13; 27- col. 15; 5).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 8 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cosmescu (US Pat. No. 6,149,648).

Regarding claims 8 and 17, Cosmescu discloses that the electrode is movable relative to the outlet. Cosmescu fails to specifically disclose that when the electrode is moved into a retracted position the guiding device closes the outlet in a substantially leakproof manner. However, it would have been obvious to one of ordinary skill in the art in view of the shapes of the electrodes show in figures 6A and 8C-D and their respective arrangement with tube **152** and mouth **154** of the embodiment of figure 5, that if the electrode was fully retracted, the outflow would be sealed/leakproof due in part to the shape of the electrode interacting with the taper on the mouth **154** (see col. 13; 27- col. 15; 5).

9. Claims 3, 6, 14-15 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cosmescu (US Pat. No. 6,149,648) in view of LaFontaine et al (US Pat. No. 5,902,328).

Regarding claim 2, Cosmescu fails to disclose that the guiding device is electrically insulating. LaFontaine discloses a similar device to that of Cosmescu (see figure 6) which comprising an electrode (electrode **102**) with a guiding device located at the distal end of the electrode (deflecting body **100**) to direct the path of an outflow of a fluid passing through the delivery device (tube **32**, fluid flow indicated by arrows in figure 7). LaFontaine further discloses for the guiding device to be comprised of an electrically insulating material (see col. 17; 5-24). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to manufacture the enlarged portion of electrode **112/346** of Cosmescu out of an

electrically insulating material as in LaFontaine to provide a device which directs the argon/plasma to only a desired treatment location and prevents damage and/or electrosurgical treatment to an area contact with or covered by the guiding device.

Regarding claim 6, Cosmescu fails to disclose the claimed configuration of the guiding device. LaFontaine discloses a similar guiding device (deflecting body **100**) which directs an outflow of fluid to a desired treatment area which has a concave configuration on a side which faces the outlet (see figure 7). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the guiding device of Cosmescu with the shape of that of LaFontaine to further direct the outputted argon gas further radially. It is further noted that Applicant has failed to set forth any criticality or unexpected results which would render the provision such a shape as a non-obvious variant.

Regarding claim 14, Cosmescu fails to disclose the claimed configuration of the guiding device. LaFontaine discloses a similar guiding device (deflecting body **100**) which directs an outflow of fluid to a desired treatment area and which has a concave surface at a surface facing the outlet of the gas-delivering device and a flattened surface at a surface facing away from the outlet of the gas-delivering device and wherein a transitional region between the concave surface and the flattened surface has a rounded contour (see figure 7; it is noted that the face of **100** which faces away from the outlet of LaFontaine is seen by the Examiner, due in part to its reduced curvature in comparison to the edges of **100,** as being flattened). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the guiding device of Cosmescu with the shape of the that of LaFontaine to further direct the outputted argon gas further radially and prevent mechanical damage to tissue in the instance

that the guiding device contacts tissue. It is further noted that Applicant has failed to set forth any criticality or unexpected results which would render the provision such a shape as a non-obvious variant.

Regarding claim 15, Cosmescu fails to disclose the claimed configuration of the guiding device. LaFontaine discloses a similar guiding device (deflecting body **100**) which directs an outflow of fluid to a desired treatment area and which has a concave surface at a surface facing the outlet of the gas-delivering device and a substantially hemispherical surface at a surface facing away from the outlet of the gas-delivering device (see figure 7; it is noted that the curved shape of **100** of LaFontaine is seen by the Examiner, due in part to its curved shaped, as being substantially hemispherical).

Regarding claim 18, Cosmescu discloses the electrode **112** and its enlarged distal portion functioning as the guiding device to be electrically conductive and to provide radiofrequency treatment and/or argon plasma treatment to a target site (see col. 13; 23- col. 15; 5). As such, it would be inherent that such an electrode assembly as that of Cosmescu would be comprised of a thermally stable material in order to provide the disclosed treatment. Cosmescu fails to disclose that the guiding device is both thermally stable and electrically insulating. LaFontaine discloses a similar device to that of Cosmescu (see figure 6) which comprising an electrode (electrode **102**) with a guiding device located at the distal end of the electrode (deflecting body **100**) to direct the path of an outflow of a fluid passing through the delivery device (tube **32**, fluid flow indicated by arrows in figure 7). LaFontaine further discloses for the guiding device to be comprised of a thermally stable and electrically insulating material (see col. 17; 5-24, TEFLON). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to

manufacture the enlarged portion of electrode **112/346** of Cosmescu out of a thermally stable and electrically insulating material as in LaFontaine to provide a device which directs the argon/plasma to only a desired treatment location and prevents damage and/or electrosurgical treatment to an area contact with or covered by the guiding device.

Regarding claim 19, both Comescu and LaFontaine fails to disclose the guiding device to be comprised of a ceramic. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to a ceramic material as the guiding device, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Additionally, Applicant has failed to set forth any criticality or unexpected result which would render the use of a ceramic material as a non-obvious variant.

Regarding claim 20, Cosmescu discloses an argon plasma coagulating probe assembly (as best seen in figures 5-6C and 8) comprising a tube (tube **152**), an electrode (electrode **112/436**) disposed substantially coaxially with the tube (see arrangement of tube/electrode in figures 5 and 8) and functioning to generate a high-frequency current wherein a distal end of the electrode projects outward through an outlet of the tube (see distal end in figures 5 and 8) and a guiding device disposed at the distal end of the electrode (enlarged portion of electrode **112/436**, see figures 6A and 8C-D) wherein the guiding device functions to guide an inert gas stream flowing through the tube, is comprised of a thermally stable material (see reasoning for rejection of claim 3 above), and is further configured to prevent mechanical damage if the guiding device touches the tissue (rounded tube-shape of electrode **112** and ball shape of electrode **436**). Cosmescu fails to disclose the concave configuration of the guiding device. LaFontaine discloses a similar

guiding device (deflecting body **100**) which directs an outflow of fluid to a desired treatment area which has a concave configuration on a side which faces the outlet (see figure 7). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the guiding device of Cosmescu with the shape of that of LaFontaine to further direct the outputted argon gas further radially. It is further noted that Applicant has failed to set forth any criticality or unexpected results which would render the provision such a shape as a non-obvious variant.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Walbrink et al (US 5,449,356), Stoddard et al (US 6,602,249 B1)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD HUPCZEY, JR whose telephone number is (571)270-5534. The examiner can normally be reached on Monday - Friday, 9 A.M. to 5 P.M. .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ronald J. Hupczey/
Examiner, Art Unit 3739

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RJH